UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF NEW YORK

KENNETH KROL, As Administrator of the Estate of JEANETTE KROL. Deceased.

Oneida County

Index No.: EFCA2021-001626

Plaintiffs.

Case No:

-against-

THE COTTAGES AT GARDEN GROVE.

Defendant.

DEFENDANT'S NOTICE OF REMOVAL

Defendant The Cottages at Garden Grove, by and through its attorneys, hereby remove this action from the Supreme Court of the State of New York, Oneida County, to the United States District Court for the Northern District of New York pursuant to 28 U.S.C. §1441, 28 U.S. §1442(a)(1) and 1446, reserving all defenses and objections to venue.:

I. COMPLIANCE WITH PROCEDURAL REQUIREMENTS

- 1. Kenneth Krol ("Plaintiff") commenced the above-captioned action in the Supreme Court, Oneida County, New York, on July 7, 2021 Index No. 001626/2021 ("State Court Action"). A true and correct copy of the Complaint is attached hereto as **Exhibit A.**
 - 2. Defendant was served with the Summons and Complaint on August 19, 2020.
- 3. A notice of removal must be filed within 30 days after receipt by the defendant of the initial pleading setting forth the claim for relief upon which the action is based. *See* 28 U.S.C. §1446(b).) The thirty (30) day period for removal does not begin to run until the defendant has received a copy of the complaint and has been properly served. *Murphy Brothers, Inc. and*

Michetti Pipe Stringing, Inc., 526 U.S. 344, 347-348 (1999). Therefore, this Notice of Removal is timely filed under 28 U.S.C. §1446(b).

- 4. All fees required by law in connection with this notice have been filed by Defendant.
- 5. This matter is removable to this Court as the federal district for the place where the state court action is pending. *See* 28 U.S.C. § 1441(a) and 1442.
- 6. Pursuant to 28 U.S.C. § 1446(a) and Northern District rule a copy of the state court docket sheet, all process, pleadings, orders, and records served upon or filed by Defendant in the State Court Action are attached hereto as Exhibits A-B. Specifically, attached hereto are true and accurate copies of Plaintiff's Complaint (the Civil Case Cover Sheet, the Return of Service Affidavit and Summons regarding service on Defendant, and the state court docket sheet.)
- 7. Written notice of the filing of this Notice of Removal will be given to Plaintiff. A copy of this Notice of Removal will be filed concurrently herewith in the Supreme Court, Oneida County, State of New York as required by 28 U.S.C. § 1446(b). No hearing has been set in the State Court Action as of the time of filing of this Notice of Removal.
- 8. By filing this Notice of Removal, Defendant does not waive any rights or defenses which may be available to Defendant.

II. STATEMENT OF FACTS

A. The Public Readiness and Emergency Preparedness Act

9. On January 31, 2020, the Secretary of Health and Human Services declared that the 2019 novel coronavirus ("COVID-19") is a public-health emergency for the United States. The United States Department of Health and Human Services ("HHS") is the lead agency for the federal government's response to the COVID-19 pandemic.

10. The Public Readiness and Emergency Preparedness ("PREP") Act was enacted by Congress and authorized by HHS, through issuance of a Declaration, to direct and otherwise utilize the private resources of entities, such as Defendant, that are part of the nation's critical infrastructure during a national public health crisis through a nationwide structure of "Authorities Having Jurisdiction" ("AHJ").¹ 42 U.S.C. §§247d-6d, 247d-6e.

11. Specifically, the PREP Act provides that, under an HHS PREP declaration, any claim for loss caused by, arising out of, relating to, or resulting from the administration to of the use by an individual of a covered countermeasure, ² a COVID-19 countermeasure, countermeasure program, or countermeasure facility, such as Defendant and those countermeasures utilized by Defendant, shall give rise only to an "exclusive federal cause of action" in an "exclusive federal jurisdiction" and shall be otherwise barred. §§247d-6d(a)(1) (providing "suit and liability" immunity), (d)(1) (providing an "exclusive Federal cause of action"), (e)(1) (providing "exclusive federal jurisdiction").

12. Unlike other such public health threats, COVID-19 had no vaccine or effective treatment for nearly a year. The most effective countermeasures to mitigate and prevent the spread of the novel and deadly COVID-19 virus were the covered countermeasures when used by and

¹ An AHJ is a "public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical ... or functional ... range or sphere of authority." Declaration, 85 Fed. Reg. 15,198, 15,202 (Mar. 17, 2020); *see also* Fourth Amended Declaration, 85 Fed. Reg. 79,190, 79,197 (Dec. 3, 2020) (AHJs include "federal, state, local ... authorities and institutions acting on behalf of governmental entities" and directing PREP Act participants regarding COVID-19 countermeasures and COVID-19 mitigation efforts).

² A "covered countermeasure" is a preventative measure that mitigates or prevents the transmission of COVID-19. § 247d-6d(i)(1); Declaration, 85 Fed. Reg. at 15,202 (Covered Countermeasures include any designated device used to treat, diagnose, cure, prevent, or mitigate COVID-19, or any device used in the administration of any such product); Second Amended Declaration, 85 Fed. Reg. 35,100, 35,102 (June 8, 2020) ("covered countermeasures" include those measures used to limit the harm that COVID-19 might otherwise cause and any device used in the administration of such measure). The "covered countermeasures" include personal protective equipment ("PPE") such as face masks, respirators, gloves, gowns, thermometers, and COVID-19 tests, as well as medications that are approved for emergency use.

administered to those who came in contact with susceptible persons, as well as when used by and administered to susceptible persons.

13. In response to the COVID-19 global pandemic, on March 17, 2020, the Secretary of the HHS issued a Declaration announcing that "[l]iability immunity as prescribed in the PREP Act...is in effect" for any "[a]ctivities authorized in accordance with the public health and medical response of the [AHJ] to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures following a Declaration of an emergency" related to COVID-19. Declaration, 85 Fed. Reg. at 15,201.

14. The Declaration defined "administration" broadly to extend beyond the physical distributions of COVID-19 countermeasures to the "management and operation of countermeasure programs, or management and operation of locations for [the] purpose of distributing and dispensing countermeasures." *See id.* at 15,202.

15. HHS has since issued six Advisory Opinions and nine amendments spanning two presidential administrations regarding the evolving COVID-19 crisis and its national coordinated response. These amendments and Advisory Opinions instruct that the PREP Act is to be interpreted and applied expansively. These, too, much like the virus itself, have evolved and, unsurprisingly, have only grown broader since the pandemic was formally declared approximately eighteen months ago.

16. Specifically, HHS has constantly reiterated that PREP's immunity and preemption clauses are to be broadly applied to state law suits.³

³ HHS refers eight times to the broad applicability of preemption of state law claims. *See* Advisory Opinion 21-01, 1; Advisory Opinion 20-04, 3 (Oct. 23, 2020); Advisory Opinion 20-02, 4–5 (May 19, 2020); Advisory Opinion 20-01, 2 (May 19, 2020). In addition, HHS refers six times to the broad applicability of immunity from state law claims. *See* Advisory Opinion 20-04, 1–2; Advisory Opinion 20-01, 2, 4, 7.

17. Notably, the Fourth Amended Declaration, Advisory Opinion 20-04, and Advisory Opinion 21-01 confirm that the PREP Act is invoked by allegations of "use" or administration of countermeasures, as well as the alleged *failure* to act or inaction, where the non-use was the result of conscious decision-making by a covered entity or person. Fourth Amended Declaration, 85 Fed. Reg. at 79,191 ("there can be situations where not administering a covered countermeasure ... can fall within the PREP Act"); Advisory Opinion 20-04, 6-7 (rejecting "non-use" reasoning in example of program planner's decision to not utilize a countermeasure in accordance with AHJ guidance—non-use reasoning is "wrong"); Advisory Opinion 21-01, 4 (Jan. 8, 2021) (discussing countermeasure decision-making as the "grist" of program planning); *see also \$247d-6d(c), (e) (Congress expressly and repeatedly applies the PREP Act to "acts and *omissions*" (emphasis added)).

18. Indeed, in the most recent two Amendments, the Eight Amendment to the Declaration, dated August 4, 2021, and the Ninth Amendment, dated September 14, 2021, HHS Secretary Xavier Becerra reaffirmed that:

The plain language of the PREP Act makes clear that there is preemption of state law as described above. Furthermore, preemption of State law is justified to respond to the nation-wide public health emergency caused by COVID-19 as it will enable States to quickly expand the vaccination, treatment and prevention workforces with additional qualified healthcare professionals where State or local requirements might otherwise inhibit or delay allowing these healthcare professionals to participate in the COVID-19 countermeasure program.

Ninth Amended Declaration (Sep. 14, 2021), p. 51162-63.

⁴ Note that the Secretary has determined that the Declaration is to be read in conjunction with the Office of General Counsel's Advisory Opinion, thereby incorporating said Advisory Opinions into the Declaration, which Congress has directed is controlling and, alternatively, requiring the Court to grant them *Chevron* and *Auer* controlling deference. *See Chevron U.S.A., Inc. v. Nat. Resource Defense Council*, 467 U.S. 837, 843–44 (1984); *Auer v. Robbins*, 519 U.S. 452, 461 (1997) (agency's interpretation of its own regulations are controlling unless "plainly erroneous or inconsistent with the regulation").

- 19. Adopting guidance found in the Office of General Counsel's May 19, 2020 Advisory Opinion (see n.3, *supra*), the Secretary likewise cautions that certain facets of the PREP Act, there, specifically, the congressional delegation of authority to HHS to define "qualified persons" under the Act, would be a "nullity" if the PREP Act were not read to preempt state law *Id.*, p. 51162.
- 20. This notion unambiguously justifies removal on the basis of preemption, both because state tort claims are completely preempted by the federal statutory and regulatory structure, and because it invokes federal officer removal.
- 21. Any view that the PREP Act does not encompass alleged omissions to use covered countermeasures "clashes with the plain language of the PREP Act, which extends immunity to anything 'relating to' the administration of a covered countermeasure." Advisory Opinion 21-01, 3. Additionally, Advisory Opinion 21-01 also states that "[t]he PREP Act is a 'Complete Preemption' Statute," because it establishes both a federal cause of action and administrative claim as the only viable remedy and vests exclusive jurisdiction in federal court. *Id.* at 2; *see also* §§247d-6d(c)(2)(A), (c)(2)(B).

B. The United States Department of Health and Human Services

22. Once COVID-19 began its rapid spread, the federal government declared that healthcare providers, such as Defendant, were "critical infrastructure" businesses obligated to aid the federal government in preventing the spread of COVID-19 during the unprecedented national emergency by following the federal government's direction under close supervision.⁵

⁵ See generally Essential Services and Activities During COVID-19 Emergency, Executive Order No. 20-91, available at https://www.flgov.com/wp-content/uploads/orders/2020/EO_20-91-com pressed.pdf (last visited Apr. 28, 2021) (expressly naming assisted living facilities as "essential" business); see also Memorandum on Identification of Essential Critical Infrastructure Workers During COVID-19 Response, CISA.gov, available at

23. The nation's critical infrastructure is "so vital to the United States that [its] incapacity or destruction...would have a debilitating impact on security, national economic security, national public health or safety, or any combination of those matters." 42 U.S.C. §5195c(e).

24. During the COVID-19 pandemic, the federal government instructed members of the healthcare critical infrastructure, such as Defendant, to carry out the duties of the government to prevent and mitigate the spread of the novel virus and to ensure the continued provision of "services critical to maintaining the national defense, continuity of government, economic prosperity, and quality of life in the United States." *Id.*; §5195c(b)(3).

25. In response to the nationwide PPE shortage, the Federal Emergency Management Agency ("FEMA") worked closely with businesses designated as "healthcare/public health" critical infrastructure to address the need for PP E and other critical supplies to continue operations in accordance with CDC guidance.⁶ Also, at the very beginning of the COVID-19 crisis in the United States, the federal government enlisted nursing facilities and assisted living communities in its efforts to fulfill the government's task of ensuring that these facilities could assist in the safe transfer and admission of patients between healthcare facilities during the pandemic.

26. As a nursing home housing some of the nation's most COVID-19 vulnerable citizens, Defendant was a qualified person and a program planner under the PREP Act, working under and directed by HHS and its AHJ network. Declaration, 85 Fed. Reg. at 15,202; *see also* HHS Response Letter, 1 (Aug. 14, 2020); §§247d-6d(i)(6) (defines a "program planner" as a person

https://www.cisa.gov/sites/default/files/publications/CISA-Guidance-on-Essential-Critical-Inf rastructure-Workers-1-20-508c.pdf (last visited Apr. 28, 2021).

⁶ Congress expressly approved and supported the role of the federal government in overseeing the operation of "critical infrastructure" skilled nursing homes and assisted living communities by allocating additional funding to such healthcare providers under the Coronavirus Aid, Relief, and Economic Security ("CARES") Act, Pub.L. 116–136, to accommodate their ongoing operations in light of the pandemic.

who supervises or administers a countermeasure program plan and facility/location), (5) (defines a "person" to include a "private corporation"); Declaration, 85 Fed. Reg. at 15,200 (explaining role of program planner in COVID-19 response).

C. Plaintiff's Complaint

- 27. Plaintiff's Complaint brings state law claims asserting that Defendant failed to implement proper COVID-19 protocols to avoid the decedent having contracted COVID-19, and failed to properly treat the decedent for COVID-19. While the Complaint does not expressly use terminology found in the PREP Act lexicon, it nevertheless asserts claims against Defendant in the context of its care and administration of COVID-19 countermeasures to decedent during the COVID-19 pandemic, and its decisions as a program planner. *See generally* Compl. Consequently, while Plaintiff purports to bring these claims under state law, the allegations necessarily implicate Defendant's use and administration of covered countermeasures, its operation and management of a covered countermeasure program, and its operation and management of a covered countermeasure location/facility, all of which is controlled by federal law under the PREP Act. Compl. ¶ 128.
 - 28. Plaintiff alleges that decedent resided at the facility during the pandemic. Compl. ¶ 12.
- 29. In addition, Plaintiff states Defendant is a licensed nursing home in New York. *See* Compl. ¶¶ 18.
- 30. Plaintiff questions the adequacy of Defendant's administration and use of COVID-19 countermeasures (as inadequate or untimely), as well as its operation and management of a COVID-19 countermeasure program. Compl ¶ 14, 122,128.
- 31. Plaintiff's Complaint brings into question the sufficiency of Defendant's use and administration of covered countermeasures, such as PPE (including facemasks), thermometers,

and tests, to prevent and mitigate the spread of COVID-19, as well as Defendant's management and operation of its countermeasure program that includes monitoring, screening, and testing patients, employees, and visitors and implementation and application of its policies and procedures. Compl. ¶¶ 128.

III. FEDERAL JURISDICTION EXISTS UNDER 28 U.S.C. §1442(a)(1)

- 32. Removal is proper under §1442(a)(1) when a defendant is sued for acts undertaken at the direction of a federal officer so as to protect the federal government from state interference with its operations, including when that federal government operation is conducted through private surrogates, such as Defendant. *See Agyin v. Razmzan*, 986 F.3d 168, 174 (2d Cir. 2021).
- 33. Whenever a suit in state court is commenced on the basis of an act "under color of federal office, regardless of whether the suit could originally have been brought in federal court," the right of federal officer removal is "absolute." *Willingham v. Morgan*, 395 U.S. 402, 406 (1969).
- 34. Unlike the general removal statute, the federal officer removal statute -- §1442(a) -- is to be "broadly construed" in favor of a federal forum. *Osterhout v. Air & Liquid Systems Corp.*, 5:14-CV-208 (MAD/DEP), 2014 U.S. Dist. LEXIS 75343, *7 (N.D.N.Y. May 30, 2014); *see also New York v. M & E Tech. Services, LLC*, 2009 U.S. Dist. LEXIS 78817, *11 (N.D.N.Y. Sep. 1, 2009). The Supreme Court has made clear that "the statute must be liberally construed," and the inquiry "depends heavily on the facts of each case and the particular conduct giving rise to the plaintiff's cause of action." *Yeend v. Akima Global Services, LLC*, 2021 U.S. Dist. LEXIS 158408, *17 (N.D.N.Y. Aug. 23, 2021) (quoting *Watson v. Philip Morris Co.*, 551 U.S. 142, 147 [2007]). Removal will be appropriate in cases that "involve defendants working hand-in-hand with the

federal government to achieve a task that furthers an end of the federal government." *Yeend*, at **17-18 (quoting *Agvin*, 986 F.3d at 176-77.

35. In the Second Circuit, to avail oneself of section 1442(a)(1), "a defendant who is not himself a federal officer must demonstrate that (1) the defendant is a 'person' under the statute, (2) the defendant acted 'under color of federal office,' and (3) the defendant has a 'colorable federal defense.'" *Cuomo v. Crane Co.*, 771 F.3d 113, 115 (2d Cir. 2014).

A. All Requirements for Removal under § 1442(a)(1) are Satisfied

36. Since the COVID-19 pandemic began, HHS and its AHJs, like the CDC and CMS, have been guiding operational decisions related to clinical infrastructure of facilities such as Defendant. *See* discussion, *supra*.

37. Facilities were ordered to restrict visitation, cancel communal dining, and implement active screening of residents and staff for fever and respiratory symptoms.⁷

38. Facilities were instructed on which residents and staff to test for COVID-19, under what circumstances to use and how to conserve PPE, when to permit staff who had COVID-19 to return to work, how to mitigate staff shortages including when to permit COVID-19 positive but asymptomatic staff to return to work, and how to handle the isolation of residents infections with COVID-19 and those under investigation for COVID-19. These very detailed directives represented a marked departure from the typical regulatory structure which existed before the pandemic.

⁷ E.g., CDC, Strategies for Optimizing the Supply of Facemasks (updated Mar. 17, 2020); CDC, Using Personal Protective Equipment (updated Aug 19, 2020); Exec. Order No. 20-009, In Re: Suspension of Statutes, Rules, and Orders Pursuant to Executive Order Number 20-52, Made Necessary by the COVID-19 Public Health Emergency; Exec. Order No, 20-52, Emergency Management-COVID-19 Public Health Emergency.

- 39. Here, Defendant satisfies the first element for federal officer removal because, as part of the country's critical infrastructure, Defendant acted at all relevant times "to assist, or to help carry out, the duties or tasks of the federal superior," by helping the federal government "fulfill other basic governmental tasks" that otherwise "the Government itself would have had to perform," *Watson v. Philip Morris Cos.*, 551 U.S. 142, 153-54 (2007). *See Wazelle v. Tyson Foods, Inc.*, No. 20-cv-203 (N.D. Tex. June 25, 2021), (designation as critical infrastructure significant in finding that private entity acting under federal officer during the early and rapidly developing days of the COVID-19 pandemic); *Fields v. Brown*, No. 6:20-cv-00475, 2021 WL 510620 (E.D. Tex. Feb. 11, 2021) (same).
- 40. Defendant also satisfies the "nexus" or "causation" requirement for federal officer jurisdiction, which requires that the alleged conduct have been undertaken "for or relating to" a federal office. To meet this requirement, "it is sufficient for there to be a connection or association between the act in question and the federal office." *In re Commonwealth's Motion to Appoint Counsel Against or Directed to Def. Ass'n of Phila.*, 790 F.3d 457, 471 (3d Cir. 2015). *See Latiolais v. Huntington Ingalls, Inc.*, 951 F.3d 286, 292 (Congress "broadened federal officer removal to actions, not just causally connected, but alternatively connected or associated, with acts under color of federal office." As the *Wazelle* court pointed out, a direct causal nexus no longer governs. 2021 WL 2637335, at *5.
- 41. The very nature of Plaintiff's Complaint demonstrates a connection or association between the act in question and the federal office. Plaintiff takes issue with Defendant's COVID-19 disease control countermeasures, as well as its policies, practices, and procedures, and how it managed and operated a COVID-19 countermeasure program and ran the facility in which such program was administered.

- 42. Again, while Plaintiff's Complaint frames the allegations such that they are intended to fall within state law tort causes of action, the Complaint cannot be read without questioning the sufficiency of Defendant's use and administration of covered countermeasures, such as facemasks, thermometers, FDA-approved medications, and tests to prevent and mitigate the spread of COVID-19. *See* Compl. ¶ 128. As a result, an analysis of the Plaintiff's claims in the context of the decedent's care provided by Defendant, whose activities fall within the scope of the PREP Act and its explicit preemption provisions, yields the inescapable conclusion that the matter belongs in federal court. This is consistent with the unambiguous guidance and opinions repeated on numerous occasions by HHS.
- 43. "[L]ogically, the choice of what safety precautions should be taken—such as whether personal protective equipment should be provided or what social-distancing measures should be adopted—is connected" to allegations that a defendant failed to keep a facility safe from COVID by taking measures compliant with relevant federal directives. *Wazelle*, 2021 WL 2637335, at *5; *see also Fields*, 2021 WL 510620, at *4.
- 44. Given that the federal government approved and directed the use of COVID-19 countermeasures by Defendant as well as approved and directed Defendant's operations in managing its response to the pandemic, and given those very countermeasures and operations are listed in the Complaint as allegedly having caused the death of Ms. Krol, Defendant has shown a "causal nexus" between Plaintiff's claims and the federal conduct for which it is protected. *Isaacson v. Dow Chem. Co.*, 517 F.3d 129, 138 (2d Cir. 2008).
- 45. Finally, for purposes of removal, Defendant presents a colorable defense based on federal law: the defense must only be "colorable," and need not be "clearly sustainable," as the purpose for the removal statute is to assure that the validity of the defense is tried in federal court.

Willingham v. Morgan, 395 U.S. 402, 407 (1969). "[O]ne of the most important reasons for removal is to have the validity of the defense of official immunity tried in a federal court;" for this reason, the Supreme Court has "rejected a narrow, grudging" approach when analyzing whether a defendant had raised a colorable federal defense. Jefferson Cty. v. Acker, 527 U.S. 423, 431 (1999). A defendant need only show it has a plausible federal defense. See, e.g., Clayton v. Air & Liquid Systems Corp., 13CV847A, 2013 U.S. Dist. LEXIS 176517, **17-18 (W.D.N.Y. Nov. 13, 2013). Defendant asserts a federal defense in this case—namely, immunity and preemption under the PREP Act for its administration and use of "covered countermeasures" in caring for decedent during the pandemic. In doing so, Defendant satisfies the "colorable federal defense" element of the federal officer removal statute.

46. Accordingly, as *Wazelle* and *Fields* recognized, federal court is the proper forum for this case because Defendant was "acting under the direction of multiple federal agencies" as part of the federal "critical-infrastructure designation" "since [the declaration of a national emergency on] March 13, 2020," *Fields*, 2021 WL 510620, at *3 & n.1, and Defendant "exhibited 'an effort to help assist, or carry out, the duties and tasks of the federal superior." *Wazelle*, 2021 WL 2637335, at *4 (quoting *Watson*, 551 U.S. at 152).

IV. FEDERAL QUESTION JURISDICTION EXISTS BY VIRTUE OF COMPLETE PREEMPTION UNDER THE PREP ACT.

47. This case is also removable under \$1441(a) on the basis of "original jurisdiction" because Plaintiff's Complaint asserts a claim "arising under" federal law within the meaning of \$1331, as Plaintiff's allegations invoke the exclusive federal cause of action, exclusive federal jurisdiction, the immunities from suit and liability, and the preemption of state law promised in

the PREP Act. *See* 42 U.S.C. §§247d-6d(a)(1) (immunity), (b)(8) (preemption), (d)(1) (federal cause of action), (e)(1) (federal jurisdiction).

48. Congress provided an exclusive remedy for the substance of the allegations and relief sought in Plaintiff's Complaint and federal law expressly preempts state law for purposes of federal questions jurisdiction. *See* 42 U.S.C. §§ 247d-6d, 247d-6e.

49. In codifying the PREP Act, Congress intended to regulate a national response to a pandemic and federalize any litigation fallout for its private partners' assistance in that effort as is evidenced by its affirmative divesture of presumed state court concurrent jurisdiction. *Id.* Congress accomplished this by designing an exclusive federal complex, comprehensive statutory scheme to ensure PREP Act claims will be heard and maintained in the federal court system (§§247d-6d (d)(1), (e)(1)), instead of an additive or supplemental action to a panoply of state law claims. *See Franchise Tax Bd. v. Constr. Laborers Vacation Tr. for S. Cal.*, 463 U.S. 1 (1983); *Tafflin v. Levitt*, 493 U.S. 455 (1990); *Yellow Freight Sys., Inc. v. Donnelly*, 494 U.S. 820, 823 (1990); *see also In re WTC Disaster Site*, 414 F.3d 352, 371 (2d Cir. 2005).

50. Moreover, the PREP Act expressly satisfies the *Beneficial* test of preemption. The Supreme Court has succinctly stated the two-part test for complete preemption and removal jurisdiction: 1) whether Congress has provided an "exclusive federal cause of action"; and 2) whether Congress "sets forth procedures and remedies governing that cause of action". *Beneficial Nat'l Bank v. Anderson*, 539 U.S. 1, 8 (2003). Specifically, the PREP Act establishes a prelitigation no-fault administrative monetary fund for those injured by the use or administration of covered countermeasures that must be exhausted prior to relief under the federal civil claims process (§§247d-6e(a) (publicly funded CCPF for "purposes of providing timely, uniform, and adequate compensation to eligible individuals for covered injuries"), (d)(1) (required exhaustion

of administrative process prior to pursuing litigation in D.D.C.), (d)(2) (tolling of statute of limitations), (d)(4) ("exclusivity" of federal administrative remedy except for litigation in D.D.C.), (d)(5) (election to accept administrative compensation or proceed to litigation claim in D.D.C.); see also 42 C.F.R. §§110.1–110.100 (regulations related to administrative claims process)).

51. The PREP Act also provides for an exclusive and comprehensive Federal cause of action as the single exception to immunity (42 U.S.C. §247d-6d(d)(1)) with its own litigation scheme (§§247d-6d(a)(2) (scope and accrual of claims for loss), (c)(1) (liability standard of willful misconduct), (c)(3) (burden of proof), (d)(1) (singular "Exception To Immunity Of Covered Persons" setting forth "exclusive federal cause of action"), (e)(1) (exclusive federal jurisdiction), (e)(2) (choice of law provision), (e)(3) (pleading standard of particularity), (e)(4) (pleading requirements of verification and certain materials), (e)(5) (congressional creation of a "three-judge court" in the D.D.C. and direct appeal to Supreme Court from an order granting or denying injunction), (e)(6) (motions practice and discovery process), (e)(7) (parameters for recoverable damages and collateral source issues), (e)(8) (noneconomic damages allowed), (e)(9) (Rule 11 sanctions), (e)(10) (interlocutory appeal process in the United States Court of Appeals for the District of Columbia Circuit)).

52. This statutory frame expressly provides for both an "exclusive" and comprehensive Federal cause of action, an "exclusive" Federal jurisdiction in the D.D.C. and an "exclusive" Federal administrative claims process thereby amply meeting the *Beneficial* two-prong test. *Beneficial*, 539 U.S. at 8. *See also Rachal v. Natchitoches Nursing & Rehab Center LLC*, 1:21-CV-00334, 2021 U.S. Dist. LEXIS 105847 (W.D. La. April 30, 2021) (finding the PREP Act is a complete preemption statute).

53. Congress clearly manifested the intent to preempt state law with respect to claims that invoke PREP Act immunity and to create and exclusive federal remedy for such preempted claims, thereby "completely preempting" state law for purposes of federal question jurisdiction.

A. Plaintiff's Claims Fall Within the Purview of the PREP Act

54. Based on the face of Plaintiff's Complaint, the totality of the allegations made therein, and the logical impact of its most central allegations, the PREP Act is implicated by Plaintiff's claims against Defendant as "covered persons" engaged in "recommended activities" under the Act. *See* §247d-6d (b)(1); Compl. ¶¶ 18, 128.

55. Defendant is a "covered person" under the PREP Act because it is a nursing home licensed by the State of New York and because it was following the guidance of AHJs when administering and using covered countermeasures, and making decisions to such use and administration in managing and operating a COVID-19 countermeasure program plan and location/facility. *See* §247d-6d(i)(2); Advisory Opinion 20-04; Response Letter, 1 (declaring Senior Living Communities as "program planners" and "qualified persons" under the PREP Act, which manage and operate COVID-19 countermeasure programs and/or COVID-19 countermeasure facilities).

56. Specifically, Defendant meets the requirements of a "program planner" of countermeasures under the PREP Act, and it is also "qualified persons who prescribed, administered or dispensed" a countermeasure under the PREP Act. *See* §247d-6d(i)(2); Advisory Opinion 20-04. Defendant was acting as a "program planners" that supervised the infection control program, under which FDA-approved PPE, such as face shields and masks, gloves, and gowns, as well as diagnostic countermeasures, sanitizers and disinfectants, were distributed and administered

to staff and residents of the facility in an effort to diagnose, mitigate, and prevent COVID-19 as expressly provided for in §247d-6d(i)(6).

- 57. Defendant's employees were acting as employees of a "program planner" that supervised and administered the infection control program that provided and administered FDA approved countermeasures among patients and staff. Policies and procedures and protocols were enacted, which are alleged by Plaintiff to have been deficient. *See* Compl. ¶128; *See also* Policies and Procedures, Exhibit B.
- 58. Defendant's employees also were also acting as "qualified persons" under §247d-6d because the employees were authorized to administer, deliver, and use FDA covered countermeasures, such as PPE and FDA approved COVID-19 devices and diagnostic tests, to diagnose and prevent COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom. *See* Advisory Opinion 20-04.
- 59. "Congress may so completely pre-empt a particular area that any civil complaint raising this select group of claims is necessarily federal in character." *Metropolitan Life Ins. Co. v. Tayor, Gen. Motors Corp.*, 481 U.S. 58, 63–64 (1987).
- 60. Because Defendant acted in their statutory role as program planners to make reasonable choices and "reasonably" follow AHJ guidance in using and allocating covered countermeasures, managing the infection control program, prioritizing the administration or use of covered countermeasures, and following applicable guidance, all of their actions, as well as any omissions, fall under the PREP Act. *See* §247d-6d(c)(4)(B) (PREP Act coverage applies to program planners who "reasonably could have believed that the countermeasure was administered or used in accordance" with the Act); *Garcia v. Welltower OpCo Group, LLC*, 2021 WL 492581 at *20–21 (2021), appealed at No. 21-55224 (9th Cir.) (noting that "OGC confirms that senior living

communities are covered persons under the PREP Act because they are 'program planners'") (citing August 14, 2020 OGC Guidance Letter); *see also* Response Letter, 1–2; *Rachal, supra*, at pp. 9-10 (recognizing that senior living communities are "covered persons" under the PREP Act).

61. Plaintiff's claims fall within the scope of the PREP Act as they are "claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure." \$247d-6d(a)(1). Plaintiff's claims arise out of Defendant's administration, allocation, use, and supervision of use, of COVID-19 countermeasures in response to the COVID-19 pandemic. Plaintiff challenges the adequacy of these countermeasures that Defendant used in fighting against COVID-19. While the Complaint is vague, by alleging that Defendant failed to take proper measures to prevent the decedent from contracting COVID-19, the Complaint's allegations are tantamount to improper use, misuse, and improper allocation and administration of PPE and implementation of segregation and isolation measures, which allegedly caused the decedent to contract COVID-19. See Compl. ¶¶ 128.

62. Plaintiff's claims are, therefore, covered under the PREP Act and are removable to federal court under the complete preemption doctrine. *Beneficial*, 539 U.S. at 8; Franchise Tax, 463 U.S. at 23–24 (removal jurisdiction is warranted where preemptive force of federal statute is "so powerful as to displace entirely any state cause of action"—such a suit is "purely a creature of federal law"). See Garcia, 2021 WL 492581; *Reilly v. Delta Healthcare II, LLC*, No: 8:21-cv-1013-JSM-JSS (M.D. Fla. June 7, 2021) (conceding applicability of PREP Act where court granted dismissal motion by senior living facility based on immunity and other protections provided under Act); *Branch v. Lilac Holdings, LLC*, No. 21-cv-00605-BAS-MDD (S.D. Cal. June 16, 2021) (same).

V. FEDERAL QUESTION JURISDICTION ALSO EXISTS PURSUANT TO THE GRABLE DOCTRINE

- 63. HHS, by and through its Fourth Amended Declaration and Advisory Opinion 21-01, also confirms that the PREP Act confers a separate, independent basis for federal question jurisdiction under the *Grable* doctrine. *See* Advisory Opinion 21-01, 4–5 (discussing *Grable & Sons Metal Prod., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 312 (2005)).
- 64. Advisory Opinion 21-01 states that "ordaining the metes and bounds of PREP Act protection in the context of a national health emergency necessarily means that the case belongs in federal court." *Id.* at 5. HHS provides that "there are substantial federal legal and policy ... interests within the meaning of [the *Grable* doctrine] in having a unified, whole-of-nation response to the COVID-19 pandemic among federal, state, local, and private-sector entities." *Id.* (quoting 85 Fed. Reg. at 79,197).
- 65. HHS further states that: "Congress delegated to [the Secretary] the authority to strike the appropriate Federal-state balance with respect to particular covered countermeasures through PREP Act declarations." *Id.*
- 66. HHS's interpretation of *Grable* is consistent with the Supreme Court's long-standing rule "that in certain cases federal question jurisdiction will lie over state-law claims that implicate federal issues." *Grable*, 545 U.S. at 312. "The doctrine captures the commonsense notion that a federal court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues." *Id*.
- 67. The *Grable* Court determined that there is no single test for determining whether an embedded federal issue exists, but that, in general, a two-step process determines whether a state

law claim "arises under" federal law: (1) the state law claim must necessarily raise a stated federal issue that is actually disputed and substantial; and (2) federal courts must be able to entertain the state law claims "without disturbing a congressionally approved balance of state and federal judicial responsibilities." 545 U.S. at 314; see also Merrell Dow Pharmaceuticals Inc. v. Thompson, 478 U.S. 804, 808 (1986).

68. Here, both prongs are satisfied. First, Plaintiff brings claims as a result for Defendant's alleged failure to "implement proper COVID-19 protocols and procedures; [] to implore and employ proper COVID-19 protocols and procedures; [and] to position plaintiff-decedent in such a manner as to avoid and/or minimize risks of contracting COVID-19." Compl. ¶ 128, which necessarily implicates disputed and substantial federal issues. *See* §247d-6d.

69. Second, as confirmed by Advisory Opinion 21-01 and the HHS Declaration, the PREP Act expresses a clear intention to supersede and preempt state control of the very issues raised by Plaintiff, i.e., issues concerning Defendant's conscious decisions when to use or administer (or not) what would fall within the scope of covered countermeasures, including COVID-19 PPE and diagnostic testing. This is evident in Congress' creation of a special three-judge federal court with a unique relationship with administrative agencies as the exclusive forum to determine pandemic issues that invoke matters of national critical infrastructure, national public health, and national security raise uniquely federal interests and questions. §247d-6d(e)(5)); see e.g. §§247d-6d(b), 247d-6d(i)(9) (referencing "security countermeasures" and the country's National Strategic Stockpile); see also Grable, 545 U.S. at 313 (the Supreme Court has "confined federal-question jurisdiction over state-law claims to those that 'really and substantially involv[e] a dispute or controversy respecting the validity, construction or effect of [federal] law") (quoting Shulthis v. McDougal, 225 U.S. 561, 569 (1912)).

70. The embedded federal question doctrine supplies removal jurisdiction in actions, such as this, that "justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues." *Grable*, 54 U.S. at 312. "[T]here is no good reason to shirk from federal jurisdiction over the dispositive and contested federal issue at the heart of the state-law claim." *Id.* at 319–320. The questions of federal surrogates and almost daily urgent federal directives, national critical infrastructure and public health threats, an exclusive federal cause of action, and a special federal court, all create substantial federal questions and require this Action's removal be sustained.

CONCLUSION

71. Because Plaintiff's claims are completely preempted by federal law, raise embedded federal questions pursuant to the *Grable* doctrine, and question the acts taken by members of the nation's critical infrastructure under the authorization of a federal officer, those claims warrant removal to federal court. Removal to this Court is therefore proper under 28 U.S.C. §1441 and § 1442.

WHEREFORE, having shown that this case is properly removable, Defendant provide

notice pursuant to 28 U.S.C. § 1446 that the State Court Action now pending in Supreme Court of

Oneida County, New York, Index No. 033889/2021, is removed to the United States District Court

for the Northern District of New York, and respectfully requests that this Court exercise

jurisdiction over this case.

Dated: September 17, 2021 Albany, New York

WILSON, ELSER, MOSKOWITZ, EDELMAN & DICKER, LLP

By: s/ Andrew S. Holland ANDREW S. HOLLAND Bar Roll 517545 LORI ROSEN SEMLIES (Pro Hac Vice Motion to be filed) Attorneys for defendant 200 Great Oaks Blvd., Suite 228 Albany, New York 12203 (518) 449-8893